

Title 64 Series 57

Department of Health and Human Resources
Bureau for Public Health
CLINICAL LABORATORY PRACTITIONER
LICENSURE AND CERTIFICATION

Summary of Amendments to the Rule:

The rule regarding Clinical Laboratory Technician and Scientist Licensure and Certification has been updated to reflect industry changes to the licensure and certification of this group of laboratory professionals. Specifically, amendments are proposed to correct obsolete language and references and to make technical corrections. Additionally, the Department proposed an amendment to the qualifying bachelor's degrees by allowing broader range of subject matter to be eligible for licensure.

Comment:

"We suggest allowing pharmacists, interns, and techs to perform COVID-19 tests and report results for pharmacies providing COVID-19 CLIA waived tests *and* allow pharmacists, interns and techs to report COVID-19 test results for pharmacies collecting specimens for COVID-19 tests to be performed at a third part licensed laboratory.

Specifically, this change would apply to:

- W. Va. Admin. Code §64-57-.1 [Prohibition; Persons Subject to Licensure; Clinical Laboratory Practitioner Trainees] prohibits any person from performing any clinical laboratory practitioner tasks, unless the person is licensed as a clinical laboratory practitioner.
- W. Va. Admin. Code §64-57-2.6 [Definitions] defines a clinical laboratory practitioner to include anyone who performs or reports laboratory tests.

During the pandemic, these waivers have allowed great expediency and tremendously improved option for the public in West Virginia. Making this change permanent will continue to allow such expediency in the Mountain State."

Response:

The Department has reviewed the comment. Personnel involved in CLIA-waived testing such as that described in the comment are exempt from the clinical laboratory personnel licensure. If such personnel wished to conduct a moderate or high complexity test, they would be come subject to licensure under 64CSR57 due to the higher level of complexity. Therefore, no changes were made to the rule in response to the comment.

Comment:

“Sub rule 5.1.d refers to requirements for licensure renewal in 5.10a. It looks like it should be referring to the revised 5.9 instead.”

Response:

The Department has reviewed the comment and had changed 5.1.d. to refer instead to 5.9.

Comment:

“I like the clarification for what would revoke a license and the process of having the Secretary be that decider at this point.”

Response:

The Department has reviewed the comment. The amended rule addresses the circumstances that can lead to revocation of a license and the remedies available to a person who has received such an adverse determination. No change has been made to the rule in response to the comment.



Robertson, April L <april.l.robertson@wv.gov>

Public Comment - Walgreens - RE: Proposed Rule 64-57

Lowe, Bryan <bryan.lowe@walgreens.com>

Thu, Jul 29, 2021 at 4:51 PM

To: "april.l.robertson@wv.gov" <april.l.robertson@wv.gov>

Good Afternoon,

Walgreens appreciates the opportunity to provide comment regarding proposed rules to Administrative Rule 64-57.

We suggest allowing pharmacists, interns, and techs to perform COVID-19 tests and report results for pharmacies providing COVID-19 CLIA waived tests *and* allow pharmacists, interns, and techs to report COVID-19 test results for pharmacies collecting specimens for COVID-19 testes to be performed at a third party licensed laboratory.

Specifically, this change would apply to:

- o W. Va. Admin. Code §64-57-4.1 [Prohibition; Persons Subject to Licensure; Clinical Laboratory Practitioner Trainees] prohibits any person from performing any clinical laboratory practitioner tasks, unless the person is licensed as a clinical laboratory practitioner.

- o W. Va. Admin. Code §64-57-2.6 [Definitions] defines a clinical laboratory practitioner to include anyone who performs or reports laboratory tests.

During the pandemic, these waivers have allowed great expediency and tremendously improved options for the public in West Virginia. Making this change permanent will continue to allow such expediency in the Mountain State.

We look forward to discussing this recommendation with agency officials throughout the rulemaking process.

Sincerely,

Bryan Lowe**Regional Director, State & Local Government Relations (DE, MD, NJ, OH, PA, VA, WV)****Walgreen Co.** | 108 Wilnot Rd., MS #1844, Deerfield, IL 60015

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Perry, Jonathan <Jonathan.Perry@camc.org>

Tue, Jul 27, 12:11 AM (1 day ago)

to me

Hello April,

The only comment I have for the lab personnel licensure rules is regarding a typo:

Sub rule 5.1.d refers to requirements for licensure renewal in 5.10a. It looks like it should be referring to the revised 5.8 instead.

I like the clarification for what would revoke a license and the process of having the Secretary be that decider at this point.

Thank you,

Jonathan Perry MLS (ASCP)CM

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